



August 21, 2001

WARNING LETTER NO. 2001-NOL-46

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mary C. Lyons, President
Southern Aire Seafood, Inc.
9626 Irvington/Bayou La Batre Highway
Irvington, Alabama 36544

Dear Ms. Lyons:

We inspected your firm, located at 9626 Irvington/Bayou La Batre Highway, Irvington, Alabama, on July 9-11, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your picked crabmeat products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of cooking time at the cooking critical control point to control pathogen survival listed in your HACCP plan for picked crabmeat. For example, the wall clock used during processing to measure cooking time is not adequately marked with minutes between the numbers.
- You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(c)(7). However, your firm did not accurately record monitoring observations at the backing critical control point to control pathogen growth and toxin formation listed in your HACCP plan for picked crabmeat. For example, for both December 1, 2000 and for December 4, 2000, there are two separate Daily Backing and Cooling Logs, each with different monitoring data for the same day.

During the inspection, our investigator documented insanitary conditions that also cause your picked crabmeat to be adulterated within the meaning of Section 402(a)(4) of the Act. They are as follows:

1. The investigator documented conditions that facilitate unsanitary operations, which are associated with the prevention of cross-contamination from insanitary objects to food contact surfaces. For example, a fly swatter was used to kill flies on several food contact surfaces that were not washed and sanitized before contacting cooked crabs.
2. The investigator documented conditions that facilitate unsanitary operations, which are associated with the adulteration of food with chemical contaminants. For example, cooked crabs routinely contacted easily removable spots of paint on the backing chute. Also, the level of chlorine in dips was not adequately monitored.
3. The investigator documented conditions that facilitate unsanitary operations, which are associated with the exclusion of pests from the food plant. For example, on July 9, 2001, there were at least six live flies in the cooking/backing area of your food plant. At least two of the flies repeatedly contacted cooked crabs, cooked crab parts, and cooked crab contact surfaces.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We are aware that you made a verbal commitment to correct violations observed at your firm. However, please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: FDA Form 483